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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/904,994	07/13/2001	Johannes Gerardus Kusters	2000.566 US	3816

7590 11/21/2005

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EXAMINER	
PORTNER, VIRGINIA ALLEN	
ART UNIT	**PAPER NUMBER**
1645	

DATE MAILED: 11/21/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/904,994	KUSTERS ET AL.	
	Examiner	Art Unit	
	Ginny Portner	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 September 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *23,26,28,30-34,37-40,44,46-50 and 52-58* is/are pending in the application.

4a) Of the above claim(s) *52-56* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *23,26,28,30-34,37-40,44,46-50 and 57-58* is/are rejected.

7)☒ Claim(s) *37-39 and 44* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claims 23, 26, 28, 30-34, 37-40, 44, 46-50, 52-58 are pending.

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Election/Restrictions

2. Newly submitted claims 55-56 and amended claims 52-54 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: All prior claims were directed to compositions claims with a recited intended use, but new claims 55-56 and 52-54 are directed to methods that utilizes specimens and a reagent, a combination not previously considered on the record and define an independent and distinct invention in light of the method steps, reagents that have different combination of structures, functions and biological effects.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 52-56 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Objections/Rejections Withdrawn

1. **Sequence Requirements**: This application contains sequence disclosures that are now in compliance with the sequence rules in 37 C.F.R. § 1.821(a)(1) and (a)(2) in light of the amendment of the Brief Description of the drawings to recite SEQ ID NOs.

*2. **Claim Rejections - 35 USC § 101Rejection Withdrawn:*** Claim 30 is now directed to an isolated and purified DNA fragment and therefore no longer reads on a product of nature.

3. ***Claim Objection Withdrawn***: Claim 26 is no longer objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. In light of the amendment of claim 23 to recite urease X and urease Y subunit

polypeptides and additional species and claim 26 depends from claim 23 and is directed to the urease X and urease Y subunit polypeptides.

4. ***Objection Withdrawn***: Claim 46 objected to because of the following informalities has been obviated through amendment of claim 46 to depend only from Claim 23.

5. ***Objection Withdrawn***: Claim 49 objected to because of the following informalities for reciting an improper Markush group format has been obviated by amendment of the claim to recite a Markush group in the format of A, B, C and D.

6. ***Objection Withdrawn*** over Claim 51; the claim has been canceled.

7. Claims 52-54 have been amended to a non-elected invention and have been withdrawn from consideration.

8. ***Rejection Withdrawn, 35 U.S.C. 112, first paragraph (Scope)*** : The rejection of claims 46-49 under 35 U.S.C. 112, first paragraph (scope) is herein withdrawn in light of the amendment canceling the claim limitations directed to host cells and polypeptides for induction of a protective immune response to immunogenic fragments.

9. **Rejection Withdrawn, 35 USC 112, second paragraph** : Regarding claim 23 and claims 24-33 no longer recite the phrase "such as".

10. **Rejection Withdrawn**, 35 USC 112, second: claim 23 rejected under 35 USC 112, second paragraph for not providing antecedent basis for the recited terms urease X and urease Y. as recited in Claim 26, has been obviated through amendment of claim 23 to recite the terms urease X and urease Y .

11. **Rejection Withdrawn**, 35 USC 112, second Claims 34 and 35-39 which depend therefrom rejected under 35 USC 112, second paragraph for reciting the "ureaseXY" in reference to the term "urease X". has been obviated by amendment of claim 34 to recite the phrase " an urease X subunit in urease XY."

12. **Rejection Withdrawn**, 35 USC 112, second Claims 40 and 41-45 which depend therefrom recite the limitation "ureaseXY" in reference to the term "urease Y" has been obviated by amendment of claim 40 to recite the phrase " an urease Y subunit in urease XY."

Response to Arguments for Objections/Rejections Maintained

13. ***Objections Maintained***: The objection to claims 37-39 to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim is traversed on the grounds that the dependent claims must include all of the limitations of the independent claim and therefore are further limiting.

14. It is the position of the examiner that while Applicant's statement is true that claims 37-39 recite all of the claim limitations of claim 34 from which they depend, the phrase "or an immunogenic fragment of said polypeptide which induces an immune response against ureaseX"

does not recite ------said immunogenic fragment------- and therefore does not refers back to the fragments defined in the independent claim which now must be 70 amino acids in length, but sets forth an additional combination of claim limitations directed to smaller fragments than 70 amino acids by reciting "an immunogenic fragment of said polypeptide, which induces an immune response". The immunogenic fragment of claims 37-39 do not refer back to the recited immunogenic fragment of claim 34, but the polypeptide of SEQ ID NO 2 or homologous polypeptides sequences of SEQ Id NO 2, and may be a fragment of any size that will induce an immune response, which could be as small as 10 amino acids. The objection to claims 37-39 is maintained because claims 37-39 broaden the scope of claim 34 which requires the fragment polypeptide to be at least 70 amino acids in length and claims 37-39 are directed to immunogenic fragments of the polypeptide of any size.

15. ***Objections Maintained***: The objection to claim 44 under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim is traversed on the grounds that the dependent claims must include all of the limitations of the independent claim and therefore are further limiting.

16. It is the position of the examiner that while Applicant's statement is true that claim 44 recites all of the claim limitations of claim 40 from which it depends, the phrase "or an immunogenic fragment of said polypeptide which induces an immune response against ureaseXY" does not recite ------said immunogenic fragment------- and therefore does not refer back to the fragments defined in the independent claim which now must be 70 amino acids in length, but sets forth an additional combination of claim limitations directed to smaller fragments than 70 amino acids by reciting "an immunogenic fragment of said polypeptide, which induces an immune response". The immunogenic fragment of claim 44 does not refer back to the recited immunogenic fragment of claim 40, but the polypeptide of SEQ ID NO 3 or homologous sequences of SEQ Id NO 3, and may be any size that will induce an immune response, which could be as small as 10 amino acids. The objection to claim 44 is maintained because claim 44 broadens the scope of claim 40 which requires the fragment polypeptide to be at least 70 amino acids in length and claim 44 is directed to immunogenic fragments of the polypeptide of any size.

17. ***Claim Rejections - 35 USC § 112 Maintained (gene therapy, nucleic acid immunization compositions):*** Claims 46-49 rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the *invention is traversed* on the grounds that "Claims 46-49 are now amended to be directed to immunogenic compositions, which are believed to be well within the skill of the art at the time the this application was filed".

18. It is the position of the examiner that claims 46-49 are directed to at least Helicobacter felis urease X or Y nucleic acid coding sequences for immunogenic fragments or immunogenic polypeptides, but the nucleic acids do not comprise any additional coding sequences operatively linked to the claimed nucleic acid molecules to transcriptional regulatory elements for expression of the encoded immunogenic epitope and no additional sequence for high expression of the nucleic acid in a mammalian cells for induction of an immune response are associated with the claimed nucleic acid molecules as well. The claims now pending are directed to bacterial nucleic acid sequences that in and of themselves would not induce an immune response that is specific to Helicobacter felis urease based upon any of the nucleic acid sequences being directly administered to the blood stream of an animal and the claims do not recite any structural regulatory elements to insure the induction of an immune response if and when the nucleic aid molecule were taken up by the appropriate eukaryotic cell to insure the encoded polypeptide is expressed to induce an immune response. Numerous factors complicate the gene therapy art which have not been shown to be overcome by routine experimentation. These include, the fate of the DNA vector itself (volume of distribution, rate of clearance into the tissues, etc.), the *in vivo* consequences of altered gene expression and protein function, the fraction of vector taken up by the target cell population, the trafficking of the genetic material within cellular organelles,

the rate of degradation of the DNA, the level of mRNA produced, the stability of the mRNA produced, the amount and stability of the protein produced, and the protein's compartmentalization within the cell, or its secretory fate, once produced. These factors differ dramatically based on the vector used, the protein being produced, and the disease being treated. Therefore, even if the specification is enabled the construction of the gene delivery vehicle comprising a cell targeting element, in the absence of particular guidance, the artisan would have been required to develop *in vivo* and *ex vivo* means of practicing the claimed methods and such development in the nascent and unpredictable gene therapy art would have been considered to have necessitated undue experimentation on the part of the practitioner.

19. ***Rejection Maintained,*** 35 U.S.C. 112, second paragraph: The rejection of claims 23, 26, 28, 30-34, 37-40, 44, 46-50, 57-58 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention for reciting the term "homologous" or homology" is traversed on the ground that :

"In addition to the discussion of homology in the Specification, Applicant's have demonstrated homology among various species of Helicobacter felis. This is reported in the figures, at the tope of Figure 1a. It is noted that specific homology within the group of isolates is 94% in all cases expect isolate 390, which is 85%. Accordingly, the degrees of homology claimed are supported in the Specification."

20. It is the position of the examiner that what is now claimed are nucleotide sequences from any source, not just Helicobacter felis, that share 85% homology with SEQ ID NO 1, and are not limited to the exemplified sequences shown in Figure 1a. The sequences claimed are not limited to the alignments shown but have been defined in the Specification to be determined by "One of the many algorithms suitable for the determination of the level of nucleic acid homology". What the algorithms for determining the nucleic acid molecules included in the scope of what is now

claimed is unclear, and the meets and bounds of the claims which recite the terms "homologous" and homology" are still unclear.

21. The rejection of the claims was not under 35 USC 112, first paragraph New Matter nor enablement, but under 35 USC 112, second paragraph. Traversal directed to "undue experimentation" is not applicable to rejections under 35 USC 112, second paragraph. The claims are still unclear based upon the various methods of determining homology within Applicant's definitions in the instant Specification. If the embodiments presented in Figure 1a are the only homologs that Applicant intends to be within the scope of the claims, then removal of the terms homolog or homologous and claiming the specific SEQ ID Nos for each of the molecules shown in figure 1a would be a claim commensurate in scope with Applicant's traversal. See In re Mayhew. The rejection is maintained for reasons of record and responses set forth herein.

22. ***Claim Rejections - 35 USC § 102 Maintained***: The rejection of claims 23, 26, 28, 30-34, 37-40, 44, 46-50, 57-58 under 35 U.S.C. 102(b) as being anticipated by Labigne et al (US Patent 5,843,460) is traversed on the grounds that the claim amendments over come the applied prior art and if not, the examiner is requested to identify the sequences which meet the claim limitations.

23. It is the position of the examiner that amended claims 23, 26, 28,30, and 46-48 are still anticipated by Labigne et al's disclosure.

24. Claims *23, 26, 28, 30-33, 46-49* is directed to compositions that comprise:

a. a nucleic acid of SEQ ID NO 1 (nucleic acid sequence);

b. a nucleic acid of at least 85 % homology with SEQ ID NO 1;

c. a part of the SEQ Id NO 1, or the nucleic acid of at least 85% homology of SEQ ID NO 1, the part encoding an immunogenic fragment, the fragment being at least 70 nucleotides in length. Immunogenic epitopes are usually 3-10 amino acids in length, thus a nucleotide sequence of 9 to 30 nucleotides would define an immunogenic portion of the part of 70 nucleotides would need to be identical to SEQ ID NO 1, or evidence a sequence that defines the immunogenic part claimed.

- Labigne et al discloses SEQ ID NO 19, which is a nucleic acid sequence of 2619 nucleotides in length, and thus is a nucleic acid that comprise a part of SEQ Id NO 1

which has 2883 nucleotides in the sequence. SEQ ID NO 19 of Labigne et al encodes a Helicobacter homologous polypeptide which shares 100% sequence identity in a number of regions of SEQ ID NO 1, which encode immunogenic parts of SEQ ID NO 1. The nucleic acid of Labigne et al encoding at least an immunogenic fragment of one of the subunit polypeptides that would induce an immune response that would immunoreact with SEQ ID NO 1. SEQ ID No 19, shares 100% sequence identity with nucleic acids 1134-1160 of SEQ ID NO 1, as well as encodes a functional homolog of the instantly claimed Helicobacter felis urease. Labigne et al still anticipates the instantly claimed invention as now claimed.

- Labigne et al's sequence SEQ Id NO 23 is a 100 amino acid polypeptide encoded by a nucleic acid molecule. The nucleic acid molecule defined by the amino acid sequence shows a nucleic coding sequence that shares 100% sequence identity over a number of regions which could induce an immune response, the nucleic acid that would encode a 100 amino acid sequence would be about 300 nucleotides and thus is a nucleic acid molecule that comprises more than 70 nucleotides. The parts of SEQ ID NO 1 that comprises a part thereof is within the region of nucleotides 206 to 505 of SEQ Id NO 1.

1. Claims 34, 37-38 and new claim 57are directed to:

* polypeptides of SEQ Id No 2,

* polypeptides that comprise an amino acid sequence that is at least 85% homology to SEQ ID NO 2,

* immunogenic fragments that comprise 70 amino acids, and will induces an immune response to urease X.

- Labigne et al's coding sequence of SEQ ID NO 19, encodes a polypeptide fragment of SEQ Id NO 2 and shares "an amino acid sequence that is at least 85% homologous to SEQ ID NO 2", and would induce an immune response to urease X (see sequence alignment provided).
- Labigne et al's sequence SEQ ID NO 23 is a polypeptide of 100 amino acids, and comprises an amino acid sequence with at least 85% homology with SEQ

ID NO 2, wherein the amino acid sequence of Labigne et al shares 100% identity over at least four amino acid sequences that share 100% identity with SEQ ID NO 2.

2. Claims 40, 44 and new claim 58 are directed to polypeptides and immunogenic compositions that comprise the polypeptides of:

- SEQ Id No 3,
- A polypeptide that comprises an amino acid sequence that is at least 85% homologous with SEQ ID NO 3;
- an immunogenic fragment that is at least 70 amino acids in length and induce an immune response to urease Y.

Labigne et al disclose a nucleic acid that encodes a polypeptide that comprises an amino acid sequence for SEQ ID NO 3 (amino acid sequence). Labigne et al SEQ ID NO 19 shares over 2200 nucleotides in common and codes for an amino acid sequence of SEQ ID NO 3 that shares at least 85% homology with "an amino acid sequence of SEQ ID NO 3", wherein the polypeptide encoded by SEQ ID NO 19, shares multiples amino acid sequences which are 100% identical to SEQ ID NO 3.

While Labigne et al does not refer to the Helicobacter felis urease which comprises two subunits, as urease subunit X and Y, the disclosed Helicobacter felis urease subunits of Labigne et al anticipate the instantly claimed invention directed to Helicobacter felis urease homologs that share a nucleic acid sequence with at least 85, 90, 94 or 97 % sequence homology with SEQ ID NO 1.

(Instant claims 31-33, 46-48) Labigne et al disclose a recombinant DNA molecule comprising a nucleotides sequence according to claim 23 under the control of a functionally linked promoter (see col. 13, lines 30-37). The recombinant DNA is incorporated into a live recombinant carrier, which includes viruses, baculovirus, vaccinia viruses, and transformation vectors (see col. 13,

lines 44-45). Among the host cells that are transformed with the nucleic acid molecule of claim 23, the DNA fragment of claim 30, the recombinant DNA of claim 31 or the live recombinant carrier of claim 32, include E.coli, Shigellae, Salmonella, Mycobacterium tuberculosis, and eukaryotic host cells (see col. 13, lines 38-51).

(**Instant claims 34-39**) Labigne et al discloses the instantly claimed Helicobacter felis polypeptide (see Labigne et al, col. 7, lines 15-32) that comprises an immunogenic fragment of SEQ ID NO 2, wherein the polypeptide is immunogenic and would induce an immune response against ureaseXY, wherein the polypeptide of SEQ ID NO 23 of Labigne et al shares 100% identity over a fragment (Labigne col. 7, lines 29-32) of SEQ ID NO 2 "KTVAQLMEE" AND "TFPDGTKL", and shares 56 identical amino acids with SEQ ID NO 2.

(**Instant claims 40-44**) Labigne et al also disclose an isolated polypeptide that comprises an immunogenic fragment, wherein the polypeptide is at least 50 amino acids in length and shares at least 97% sequence homology with an amino acid sequence of SEQ ID NO 3 (see sequence alignment with extensive regions that share 100% identity with SEQ ID NO 3).). The polypeptides/proteins are disclosed for a diagnostic test for detection of Helicobacter felis infection (see col. 12, lines 2-5 "in-vitro detection" of antibodies in a sample).

(**Instant claims 46-49**) Compositions that comprise a pharmaceutically acceptable carrier (see col. 9, lines 15-22; col. 13, lines 52-59) together with a nucleic acid, or immunogenic Helicobacter felis urease homolog, carrier or host cell (see col. 13, lines 30-59) together with an additional antigen HspA or HspB, or homolog thereof (see Labigne et al, col. 31, lines 25-50 and col. 8, lines 33-38, especially col. 31, lines 31-32) "Chlamydia" are disclosed.

Instant claim 50, Compositions of anti-Helicobacter felis urease antibodies are disclosed (cross reactive, see col 9, lines 6-14) for providing passive immunity, and therefore function as vaccine compositions comprising antibodies (see Labigne et al, col. 9, lines 27-30; see col. 10, lines 62-67, col. 11, lines 1-67 and col. 12, lines 1-5). The antibodies are disclosed for a detection of Helicobacter felis urease polypeptides in a sample (see col. 10, lines 64-67 col. 11, lines 1-19 and 20-30). Labigne et al still anticipates the instantly claimed invention.

New Grounds of Rejection

Claim Rejections - 35 USC § 112

3. Claims 1-27 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

4. The claims are directed to compositions that comprises homolog nucleic acids or polypeptides of Helicobacter felis urease XY, the homologs being claimed by the phrase "A nucleic acid molecule comprising a nucleotide sequence" …."said nucleotide sequence having at least 85% homology with SEQ ID NO 1" or by the phrase "comprising an amino acid sequence that is at least 85% homologous to SEQ ID NO 2 or an immunogenic fragment induces an immune response" but what parts or regions of SEQ ID NO 1, 2 and 3 have been chosen to be apart of the claimed nucleic acid and polypeptides has not been described, nor have the recombinant genes used to produce a plurality of protein forms of homologous urease XY, other than those shown in Figure 1a have not been described. While specific species defined by specific nucleic acid sequences and complete amino acid sequences shown in Figure 1a have been disclosed, what the claimed are nucleic acid molecules and polypeptides, that only comprise any nucleotide sequence or an amino acid sequence region, a small portion of the

sequences recited, and additionally comprise unspecified nucleic acids and amino acids to result in the claimed nucleic acid and polypeptide that will induce an immune response.

The claimed nucleic acid sequences and polypeptides are required to have comprise a sequence that encodes or has an antigenic functional characteristic to Helicobacter felis ureaseXY, but the antigenic/immunogenic region of Helicobacter felis urease XY has not been described by any specific monoclonal antibody, or to have any specific chemical structure, but only to comprise any region of the sequence that can be incorporated into a larger molecule and be reactive with any antibody reactive with Helicobacter felis ureaseXY. What has been claimed is a composition that contains within its scope a plurality of nucleic acid and polypeptide homologs or analogs to Helicobacter felis nucleic acids that encode antigens that have a single common structural region, or polypeptides that have a single common structural region but no specific biological function other than a single antigenically cross reactive region.

Applicant also broadly describes the invention as embracing any substitution, insertion or deletion of amino acids throughout the entire stretch of nucleotides or amino acids found in the reference sequence by use of language in which only a "part" or "fragment" of the reference sequence is required, but the final relative molecular weight of the resultant protein is far larger than the region that can be selected from the reference proteins. None of the proteins that comprise any antigenic region of the recited sequence and reacts with an Helicobacter felis urease antibody, but differs by any number of amino acids, and has a sequence not represented by the sequences of SEQ ID NO 1, 2 or 3 and, encode or comprise amino acid sequences that do not meet the written description provision of 35 USC 112, first paragraph. Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, makes clear that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention.* The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed.*" (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See Vas-Cath at page 1116.).

The claimed nucleic acids and polypeptides that comprise sequences other than those set forth in Figure 1a, SEQ ID NO 1, 2 or 3, and only comprise an antigenic epitope of 3-10 amino acids out of a possible 700+ amino acids fail to have an adequate written description in the instant specification. The specification does not provide original descriptive support for what the

additional amino acid sequences are, that are in association with any number of parts, fragments or regions selected from each of the recited Helicobacter sequences.

The skilled artisan cannot envision all the contemplated nucleic acid molecules or polypeptides/proteins that encode or comprise any amino acid antigenic sequence region of Helicobacter felis ureaseXY. The detailed chemical structure of the claimed genus of proteins has not been described and therefore conception cannot be not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it. A method of screening for antigenic immunoreactivity is not a method of making a protein, the product itself is required. See Fiers v. Revel, 25 USPQ2d 1601, 1606 (CAFC 1993) and Amgen Inc. V. Chugai Pharmaceutical Co. Ltd., 18 USPQ2d 1016. One cannot describe what one has not conceived. See Fiddes v. Baird, 30 USPQ2d 1481, 1483. . Thus, the written description of the instant specification does not provide for "comprising" language. Therefore, only isolated nucleic acid molecules and polypeptides of SEQ ID Nos 1, 2 and 3 and those shown in Figure 1a have been described but not the full breadth of the claim meets the written description provision of 35 USC 112, first paragraph. Applicant is reminded that Vas-Cath makes clear that the written description provision of 35 USC 112 is serviceable from its enablement provision. (See page 1115.) Applicants are directed to the Revised Interim Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, ¶ 1 "Written Description" Requirement, Federal Register, Vol. 64, No. 244, pages 71427-71440, Tuesday December 21, 1999.

5. Claims 1-20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-20 recite the phrase "comprising regions which act as antigens specific to Helicobacter pylori". As a genus of embodiments that define a plurality of regions that act as

Claim Rejections - 35 USC § 112

25. Claim 39 recites the limitation "The polypeptide of claim 31" in an effort to further limit claim 31, but claim 31 is directed to a DNA sequence. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 101

26. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

27. Claims 23, 26 and 28 are not directed to isolated and purified nucleic acid molecules and therefore do not show the hand of man; the claimed invention is directed to non-statutory subject matter. The rejection could be obviated by amending the claims to recite ------isolated and purified-----.

Claim Rejections - 35 USC § 102

28. Claims 23,26,28,30, 33,34,37-39,40,44,57,58 are rejected under 35 U.S.C. 102(b) as being anticipated by Gootz et al (1994).

Gootz et al disclose H. felis ATCC 49179 (see abstract), also known as CS-1, the same strain Applicant determined the amino acid sequence for urease as shown in Figure 1(a), SEQ Id NO 1.

Gootz et al isolated and purified the Helicobacter felis urease polypeptide (see page 794, col. 1, paragraph 5) and show antibodies immunoreactive with the polypeptides (see page 794, col. 2, paragraph 4, and Figure 3, page 795).

DNA sequences were utilized in Southern hybridizations (see probes on page 795, col. 2, paragraph 2) and the genes for H. felis urease were identified in genomic blots of H.felis ATCC

49179 (see Figure 4), thus isolating the nucleic acid coding sequences for the H. felis urease polypeptides of CS-1.

Inherently the reference anticipates the instantly claimed invention. Since the Office does not have the facilities for examining and comparing applicant's protein with the protein of the prior art, the burden is on applicant to show a novel or unobvious difference between the claimed product and the product of the prior art (i.e., that the protein of the prior art does not possess the same functional characteristics of the claimed protein). See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594

Atlas Powder Co. V IRECA, 51 USPQ2d 1943, (FED Cir. 1999) states AArtisans of ordinary skill may not recognize the inherent characteristics or functioning of the prior art...However, the discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior arts functioning, does not render the old composition patentably new to the discoverer. AThe Court further held that Athis same reasoning holds true when it is not a property but an ingredient which is inherently contained in the prior art.

Conclusion

29. This is a non-final action.

30. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ginny Portner whose telephone number is (571) 272-0862. The examiner can normally be reached on M-F, alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on (571) 272-0864.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Vgp
November 16,, 2005

L. F. Smith

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